

## **Federal Guidance on Emergency Drug Kits Containing Controlled Substances**

The following is available from the below two sources. The information below was taken from the DEA frequently asked question section (first source).

<http://www.deadiversion.usdoj.gov/faq/general.htm>

(Frequently Asked Questions from DEA Diversion website)

[http://www.deadiversion.usdoj.gov/fed\\_regs/notices/other/fr\\_04091980.pdf](http://www.deadiversion.usdoj.gov/fed_regs/notices/other/fr_04091980.pdf)

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***Question: Can an LTCF store controlled substances in an emergency kit without being registered with DEA?***

**Answer:** DEA published the following Statement of Policy in the April 9, 1980 Federal Register regarding the placement of controlled substances in an emergency kit located in an LTCF.

### **STATEMENT OF POLICY**

The placement of emergency kits containing controlled substances in non-federally registered Long Term Care Facilities (LTCF) shall be deemed to be in compliance with the Comprehensive Drug Abuse Prevention and Control Act of 1970, **if the appropriate state agency or regulatory authority specifically approves such placement and promulgates procedures which delineate:**

- A. **The source from which an LTCF may obtain controlled substances for emergency kits.** The source of supply must be a DEA registered hospital/clinic, pharmacy, or practitioner.
- B. **Security safeguards for each emergency kit stored in the LTCF** which include the designation of Individuals who may have access to the emergency kits and a specific limitation of the type and quantity of controlled substances permitted to be placed in each emergency kit.
- C. **Responsibility for proper control and accountability of such emergency kits within the LTCF** to include the requirement that the LTCF and the providing DEA registered hospital/clinic, pharmacy, or practitioner maintain complete and accurate records of the controlled substances placed in the emergency kit, the disposition of these controlled substances plus the requirement to take periodic physical inventories.
- D. **The emergency medical conditions under which the controlled substances may be administered to patients** in the LTCF to include the requirement that medication be administered by authorized personnel only as expressly authorized by an individual practitioner and in compliance with the provisions of **21 CFR 1306.11** and **21 CFR 1306.21**.
- E. **Prohibited activities which can result in the state revocation, denial, or suspension** of the privilege of having or placing emergency kits, containing controlled substances, in an LTCF.

### **IMPORTANT POINTS**

- 21 CFR 1306.11; pertains to the requirements of a CII prescription and only being able to dispense a prescription pursuant to a prescription.
- 21 CFR 1306.21; pertains to the requirements of a CIII-V prescription and only being able to dispense a prescription pursuant to a prescription.

### Additional Guidance from the American Society of Consultant Pharmacists

**Question:** When is a nurse authorized to remove a controlled drug from an e-kit?

**Answer:** Controlled drugs in e-boxes are treated the same way as all other controlled drugs. Before a drug can be removed, there must be a valid written prescription (which may be a fax) unless the emergency exception applies. E-boxes should never be used routinely to dispense drugs that should have been reordered. Rather, e-boxes should be used only for unanticipated emergencies that may be a new admission or a new order. Due to the importance of state law in authorizing the use of e-kits in long-term care, it is critical that practitioners, pharmacists and facilities understand all pertinent state laws and regulations governing e-kits, in addition to federal requirements.

**Question:** What are the potential consequences if nurse take a controlled drug from e-kit before the practitioner has issued a valid prescription?

**Answer:** Taking possession of a controlled drug without proper authorization can be a serious offense. A nurse who removes a controlled drug from an e-kit without valid authorization may be subject to civil and criminal fines and penalties, disciplinary action by the state licensing board and exclusion from federal health care programs.

**Question:** Is it permissible for a nurse to remove a controlled drug from an e-kit if s/he has received an oral order from the practitioner?

**Answer:** Some states permit this practice. However, DEA rules require that the practitioner provide oral authorization or a faxed prescription to the pharmacist before a drug is dispensed. Consequently, a practitioner who gives an oral order to the nurse in the facility by telephone must also ensure that the pharmacy receives either an oral "emergency" order or a written prescription order (which may be sent via facsimile).

**Question:** Can a nurse in a long-term care facility remove drugs from an E-kit based upon a standing order?

**Answer:** No. An e-kit should only used in an emergency situation, which by definition must be unanticipated.

**Question:** Can a nurse remove a CII from an e-kit for a patient who already has a valid prescription for a CII drug but has run out of medication at 2:00 a.m.?

Assuming this situation meets the criteria for an "emergency situation," the nurse would need to contact the practitioner for an oral authorization (which must be communicated by the practitioner to the pharmacist, either orally or by fax). While these situations sometimes cannot be avoided, nursing facilities and pharmacies should have systems in place that ensure the timely re-ordering of medications for patients with on-going need for pain management.

### **Conflicts with Current Utah Statute**

The Utah Controlled Substance Act in U.C.A. § 58-37-6 (2)(e); states:

“A **separate license is required at each principal place of business or professional practice where the applicant** manufactures, produces, distributes, **dispenses**, conducts research with, or performs laboratory analysis upon controlled substances.”

The Utah Pharmacy Practice Act in U.C.A. § 58-17b-302(3); states:

“**Each place of business shall require a separate license**. If multiple pharmacies exist at the same address, a separate license shall be required for each pharmacy.”

Also review the definition of the Practice of Pharmacy in U.C.A. § 58-17b-102.

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### **Conflicts with Current Utah Administrative Rules**

#### **R432. Health, Family Health and Preparedness, Licensing.**

##### **Rule R432-150. Nursing Care Facility.**

##### **R432-150-19. Pharmacy Services.**

- (1) The facility must provide or obtain by contract routine and emergency drugs, biologicals, and pharmaceutical services to meet resident needs.
- (2) The facility must employ or obtain the services of a licensed pharmacist who:
  - (a) provides consultation on all aspects of pharmacy services in the facility;
  - (b) establishes a system of records of receipt and disposition of all controlled substances which documents an accurate reconciliation; and
  - (c) determines that drug records are in order and that an account of all controlled substances is maintained and reconciled monthly.
- (3) The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist.
  - (a) The pharmacist must report any irregularities to the attending physician and the director of nursing or health services supervisor.
  - (b) The physician and the director of Nursing or health services supervisor must indicate acceptance or rejection of the report and document any action taken.
- (4) Pharmacy personnel must ensure that labels on drugs and biologicals are in accordance with currently accepted professional principles, and include the appropriate accessory and cautionary instructions, and the expiration date.

(5) The facility must store all drugs and biologicals in locked compartments under proper temperature controls according to R432-150-19 (6)(e), and permit only authorized personnel to have access to the keys.

(a) The facility must provide separately locked, permanently affixed compartments for storage of controlled substances listed in Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1976 and other drugs subject to abuse, except when the facility uses single unit dose package drug distribution systems in which the quantity stored is minimal and a missing dose can be readily detected.

(b) Non-medication materials that are poisonous or caustic may not be stored with medications.

**(c) Containers must be clearly labeled.**

(d) Medication intended for internal use shall be stored separately from medication intended for external use.

(e) Medications stored at room temperature shall be maintained within 59 and 80 degrees F.

(f) Refrigerated medications shall be maintained within 36 and 46 degrees F.

**(6) The facility must maintain an emergency drug supply.**

(a) Emergency drug containers shall be sealed to prevent unauthorized use.

(b) Contents of the emergency drug supply must be listed on the outside of the container and the use of contents shall be documented by the nursing staff.

**(c) The emergency drug supply shall be stored and located for access by the nursing staff.**

**(d) The pharmacist must inventory the emergency drug supply monthly.**

**(e) Used or outdated items shall be replaced within 72 hours by the pharmacist.**

**(7) The pharmacy must dispense and the facility must ensure that necessary drugs and biologicals are provided on a timely basis.**

**(8) The facility must limit the duration of a drug order in the absence of the prescriber's specific instructions.**

(9) Drug references must be available for all drugs used in the facility. References shall include generic and brand names, available strength and dosage forms, indications and side effects, and other pharmacological data.

**(10) Drugs may be sent with the resident upon discharge if so ordered by the discharging physician provided that:**

(a) **such drugs are released in compliance R156-17a-619;** and

(b) a record of the drugs sent with the resident is documented in the resident's health record.

**(11) Disposal of controlled substances must be in accordance with the Pharmacy Practice Act.**

## **IMPORTANT POINTS**

→ The practice of pharmacy definition and the above described statute prohibit anyone other than a properly licensed pharmacy from possessing stock controlled substances or legend drugs.

- The Utah Department of Health has invalid and antiquated administrative rules that supersedes what statute does not allow. Further the existing pharmacy law/ rule do not even address some of the operating standards mandated by the pharmacist and pharmacy that are to provide pharmacy services pursuant to the Department of Health Administrative Rules.
- As the Federal Register states, the emergency kits in Long Term Care Facilities are only viewed as compliant with the Controlled Substance Act **IF** the appropriate state agency or regulatory authority specifically approves such placement and promulgates procedures which delineate those 5 major operating standards. The Utah Department of Health is not the appropriate state as anything pertaining to controlled substances is defined within Title 58 and its corresponding rules. Moreover, the appropriate Utah statute conflicts with the inappropriate state agency administrative rules.
- Additionally, the existing administrative rules do not define and cover everything mandated in the Federal Register to even be considered compliant.